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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rachid Zegdi

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EXAMINER

MILLER, CHERYL L

ART UNIT

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3738

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,658	Applicant(s) ZEGDI, RACHID	
	Examiner CHERYL MILLER	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-18 is/are pending in the application.
- 4a) Of the above claim(s) 10, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-9, 11-13 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Attachment 1</u> . |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection. However, since some of the rejections have been maintained, the examiner has responded to applicants corresponding arguments.

The applicant has argued that Garrison (US 6,425,916 B1) does not disclose a centripetal compression means comprising a clamp with at least two branches connected at a common region, each branch having a connection segment connected to the shutter and a drive segment positioned between the connection segment and common region. The examiner disagrees. See attachment 1 for interpretation of Garrison's compression means. If applicant were to claim in line 13 of claim 1, the flexible shutter contracted *toward* (instead of *to*) the central axis, this would seemingly overcome the Garrison rejection.

The applicant has argued that Johnson (US 4,339,831) does not disclose drive segments, and that the branches (10, 12, 14) must be all connection segments, since they are connected to the shutter along their entire length. The examiner disagrees. Johnson shows a resilient frame (fig.1) comprising an integrated centripetal compression mean comprising a clamp with at least two branches (seen in fig.1, the branches being 10, 12, or 14). The branches (10, 12, 14) are connected at a common region (16). Each branch comprises a connection segment (top of branches at 18, 20, 22) connected to the shutter (see figs) and a drive segment (intermediate length of branches 10, 12, 14) positioned between common region (16) and connection segments (18, 20, 22). It is noted that applicant has *not* claimed the drive segments to be unattached to the shutter. If applicant were to claim that wherein the drive segments are not attached (or remain

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unattached) to the flexible shutter, *or* the drive segments spaced axially away from the flexible shutter, either of these would seemingly overcome the Johnson rejection.

Election/Restrictions

Claims 10, 14, and 15 are directed to an invention that is independent or distinct from the invention in claim 1 for the following reasons: Claims 10, 14, and 15 require a constriction strand and wire mesh frame which are a distinct embodiment from that claimed in claim 1. Claim 1 requires a clamp, seen in figures 1-3 for example, however claims 10, 14, and 15 do not have a clamp and are directed to a different embodiment (not combinable) shown in figure 8.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 10, 14, and 15 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6-9, 11, 12, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrison et al. (US 6,425,916 B1, cited previously). Garrison discloses a kit (fig.9) comprising a tubular endoprosthesis (8; fig.8) and a prosthetic valve (6; fig.10), the valve

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for removably implanting in the endoprosthesis (is unattached separate component, thus has *capability* of being removed therefrom), the valve (6; fig.10) having a resilient deformable carrier frame (26; col.8,lines 14-21; col.9, lines 1-10), flexible shutter (leaflets 38), and centripetal compression means (windings of frame 28, 30 or 32 may act as means also) for compressing the carrier frame. Garrison discloses the shutter (leaflets 38) to have an obstructed position (closed) in which it is extended transverse to the lumen (see fig.11) and a released position when the shutter is contracted transversely to the central axis (leaflets open to be parallel with lumen thus are contracted along the transverse plane-relative to the transverse plane, at the rim/perimeter of the valve). Garrison discloses the shutter (38) to be a pouch having an orifice (seen in fig.11), the kit being hemispherical at a wall (leaflets 39 form cupped surface when closed; fig.29, 30). Garrison discloses the compression means (28, 30, 32) to comprise a clamp having branches (each branch being considered a strut of 28 or 30 or 32) connected at a common region (bend in frame), the branches connected to the shutter (see fig.9, 10, 29, 30; connected at 40, 41, see fig.9, 10) in a connection segment and the branches (struts) having a drive segment (length of struts) capable of co-operating with a clamp member (has such capability of being grasped by a tool), see attachment 1. Garrison discloses the branches (struts of frame) to be welded together, fork shaped, and deformable (fig.9, 10, 29, 30). Garrison discloses the valve (6) to have threads (sutures, col.5, lines 44-48) connecting the pouch (38) to the branches (struts of frame). Such sutures (40, 41, seen in fig.9, 10, 29) may be considered the constriction strand. Garrison discloses the valve (6) disposed inside the tubular endoprosthesis (8). Garrison discloses implanting the endoprosthesis (8) and valve (6) endoluminally (fig.17-19, 23-26). The valve is considered *removable* (capable of being removed).

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If applicant were to claim the flexible shutter to be contracted **toward** the central axis, (instead of *to*-which may be interpreted as relative to or in relation to), this would seemingly overcome the Garrison rejection.

Claims 1, 2, 4, 6-9, 11, 12, and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Johnson (US 4,339,831, cited in IDS). Johnson discloses a kit comprising a tubular endoprosthesis (50; seen in fig.6) and a prosthetic valve (seen in fig.2), the valve configured to be implanted in and withdrawn from the endoprosthesis (the two are separate components, prior to suturing to the vessel wall, the valve is configured to be implanted in or withdrawn from the endoprosthesis 50), the valve comprising a resilient carrier frame (seen in fig.1) that is elastically deformable and biased to a deployed position (seen in fig.2; col.4, lines 22-25), and a flexible shutter (30) connected to the frame (see fig.2) the shutter deformable between an obstructed position which it is extended transversely (see fig.2, 3) and a released position which it is contracted transversely (see fig.5), and an integrated centripetal compression means (seen in fig.1) for compressing the frame into the folded configuration (joint 16 forms a clamp which may be grasped by an instrument to compress the frame; it acts as a means to allow compression by its shape and resiliency). Johnson discloses the shutter (30) to comprise a hemispherical pouch with an end wall (seen in fig.2). Johnson discloses the compression means to comprise at least two branches (10, 12, 14) connected at a common region (16) each branch having a connection segment (free ends 18, 20, 22) connected to the shutter, and a drive segment (intermediate portions of 10, 12, 14) positioned between the common region (16) and connection segments (18, 20, 22). Johnson discloses a plurality of threads (sutures, sewn; col.5, lines 8-12)

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connecting the branches to the pouch. Johnson discloses implanting the tubular prosthesis in a duct endoluminally and then implanting the valve inside the endoprosthesis (col.5 line 61-col.6 line7) it is considered removably implanted, as it may be surgically removed at any time).

Johnson's drive segments are convexly curved, the ends of the curve, directed inwardly. If applicant were to the claim that wherein the drive segments are not attached (or remain unattached) to the flexible shutter, *or* the drive segments spaced axially away from the flexible shutter, either of theses would seemingly overcome the Johnson rejection.

Claims 1-3, 7-9, 11-13, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Vesely (US 6,530,952 B2, cited previously). Vesely discloses a kit comprising a tubular endoprosthesis (10 or 100; fig.2, 10) and a prosthetic valve (fig.17), the valve for removably implanting in the endoprosthesis, the valve having a resilient deformable carrier frame (110; fig.12, 17; col.9, lines 33-44), flexible shutter (120; fig.17), and centripetal compression means (112) for compressing the carrier frame (col.13, lines 60-62). Vesely discloses the shutter (120) to be a pouch and having an orifice (seen in fig.27a). Vesely discloses the valve disposed inside the tubular endoprosthesis (fig.27a). Vesely discloses implanting the endoprosthesis (100) and valve (110) endoluminally (through a lumen) and removing the valve and replacing it with a new one (col.3, lines 11-12; col.5, lines 5-10; col.9, lines 1-5). Vesely's shutter (leaflets) transverse the lumen when closed and are contracted at the rim of the valve along the transverse plane when open. Vesely discloses the frame to have an integrated centripetal compression means (fig.12) comprising a clamp having at least two branches (12) connected at a common region (for example, top 136's in figs.), having a connection segment (for example bottom of 136's in figs)

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and a drive segment therebetween (length of 112's). If applicant were to claim that wherein the drive segments are not attached (or remain unattached) to the flexible shutter, *or* the drive segments spaced axially away from the flexible shutter or the shutter is contracted transversely *toward* the central axis, any of these would seemingly overcome the Vesely rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERYL MILLER whose telephone number is (571)272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cheryl Miller/
Examiner, Art Unit 3738

/Corrine M McDermott/
Supervisory Patent Examiner, Art Unit 3738